

**UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS  
AUSTIN DIVISION**

CUSTOPHARM, INC.,	)	
	)	Civil Action No. 1: 15-cv-00841-RP
	)	
Plaintiff,	)	Removed from:
	)	The District Court
v.	)	of Travis County, Texas
	)	98th Judicial District
CHEMWERTH, INC., AND JOHN DOES	)	Cause No. D-1-GN-15-003371
1-5,	)	
	)	
Defendants.	)	

**CHEMWERTH’S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant ChemWerth, Inc. (“ChemWerth”), by and through its undersigned attorneys, hereby responds to Plaintiff’s Verified Original Petition, as filed August 18, 2015, in The District Court of Travis County, and removed to the Western District of Texas, Austin Division, on September 18, 2015.

**I. NATURE OF THE ACTION**

1. ChemWerth denies the allegations in paragraph 1, except to admit that Plaintiff has alleged claims for declaratory relief and breach of contract arising out of a Service Agreement (the “Agreement”) between Plaintiff and ChemWerth.

**II. DISCOVERY CONTROL PLAN**

2. The allegations in paragraph 2 assert conclusions of law to which no response is required. To the extent a response is required, denied.

**III. PARTIES**

3. ChemWerth has insufficient information to admit or deny the allegations of paragraph 3 and leaves Plaintiff to its proof.

4. Admitted.

5. ChemWerth has insufficient information to admit or deny the allegations of paragraph 5 and leaves Plaintiff to its proof.

6. Denied.

#### **IV. JURISDICTION**

7. The allegations in paragraph 7 assert conclusions of law to which no response is required. To the extent a response is required, denied.

8. ChemWerth admits that the Agreement contains the quotation recited in paragraph 8; otherwise denied.

#### **V. VENUE**

9. The allegations in Paragraph 9 assert conclusions of law to which no response is required. To the extent a response is required, denied.

10. ChemWerth admits that the Agreement contains the quotation recited in paragraph 10; otherwise denied.

#### **VI. CONDITION PRECEDENT**

11. ChemWerth has insufficient information to admit or deny the allegations of paragraph 11 and leaves Plaintiff to its proof.

#### **VI. FACTUAL BACKGROUND**

12. ChemWerth has insufficient information to admit or deny the allegations of paragraph 12 and leaves Plaintiff to its proof.

13. Denied.

14. Denied.

15. Denied.

16. Denied.

17. Denied.

18. The allegations in paragraph 18 assert conclusions of law to which no response is required. To the extent a response is required, denied.

19. The allegations in paragraph 19 assert conclusions of law to which no response is required. To the extent a response is required, denied.

20. Defendant admits that the Agreement states, “ChemWerth shall remit said amount, or a statement verifying that no amount is due, to Custopharm within thirty (30) days after March 31, June 30, September 30, and December 31, after the Effective Date for payments received by Chemwerth in the previous quarter. Custopharm shall be entitled to compensation as set forth herein for so long as Product sales occur, regardless of whether or not this Agreement is in effect.”

21. Denied.

22. Denied.

23. The allegations in paragraph 23 assert conclusions of law to which no response is required. To the extent a response is required, denied.

24. The allegations in paragraph 24 assert conclusions of law to which no response is required. To the extent a response is required, denied.

25. ChemWerth admits that paragraph 25 contains language from Section III, Item 7 of the Agreement; otherwise denied.

26. Admitted.

27. ChemWerth admits it received written correspondence from Custopharm on June 25, 2015 and July 15, 2015 in which Custopharm indicated that it believed ChemWerth breached or violated the Services Agreement; otherwise denied.

28. Denied.

29. The allegations in paragraph 29 assert conclusions of law to which no response is required. To the extent a response is required, denied.

30. ChemWerth has insufficient information to admit or deny the allegations of paragraph 30 and leaves Plaintiff to its proof.

31. Denied.

32. ChemWerth admits that paragraph 32 contains language from Section VII, Item 1 of the Agreement; otherwise denied.

33. Denied.

34. Denied.

#### **VIII. DECLARATORY ACTION AGAINST CHEMWERTH**

35. ChemWerth hereby incorporates its responses to the paragraphs above as though fully set forth herein.

36. Admitted.

37. ChemWerth has insufficient information to admit or deny the allegations of paragraph 37 and leaves Plaintiff to its proof.

38. The allegations in paragraph 38 assert conclusions of law to which no response is required. To the extent a response is required; denied.

39. The allegations in paragraph 39 assert conclusions of law to which no response is required. To the extent a response is required; denied.

#### **IX. BREACH OF CONTRACT**

40. ChemWerth hereby incorporates its responses to the paragraphs above as though fully set forth herein.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

**X. ACTION FOR ACCOUNTING**

50. ChemWerth hereby incorporates its responses to the paragraphs above as though fully set forth herein.

51. Denied.

**XI. CONSTRUCTIVE TRUST**

52. ChemWerth hereby incorporates its responses to the paragraphs above as though fully set forth herein.

53. ChemWerth has insufficient information to admit or deny the allegations of paragraph 53 and leaves Plaintiff to its proof.

54. ChemWerth has insufficient information to admit or deny the allegations of paragraph 54 and leaves Plaintiff to its proof.

55. ChemWerth has insufficient information to admit or deny the allegations of paragraph 55 and leaves Plaintiff to its proof.

56. Denied.

57. Denied.

58. ChemWerth has insufficient information to admit or deny the allegations of paragraph 58 and leaves Plaintiff to its proof.

59. ChemWerth denies that Plaintiff is entitled to the relief requested in paragraph 59 and that Plaintiff has been damaged under the Agreement.

60. ChemWerth denies that Plaintiff is entitled to the relief requested in paragraph 60.

## **XII. ATTORNEYS' FEES**

61. The allegations in Paragraph 61 assert conclusions of law to which no response is required. To the extent a response is required, denied.

## **XIII. REQUEST FOR DISCLOSURE**

62. The allegations in Paragraph 62 assert conclusions of law to which no response is required. To the extent a response is required, ChemWerth denies that Plaintiff is entitled to the relief requested in paragraph 62.

## **PRAYER FOR RELIEF**

63. ChemWerth denies that Plaintiffs are entitled to the relief requested in the Complaint, including specifically sub-paragraphs (a) through (j) of the "Prayer for Relief."

## **ADDITIONAL AVERMENTS**

ChemWerth denies all claims and allegations not unequivocally admitted herein.

## **AND FOR AFFIRMATIVE AND OTHER DEFENSES**

ChemWerth asserts the following affirmative and other defenses, without assuming any burden of production or proof that it would not otherwise have. ChemWerth reserves the right to assert additional defenses as they may become known during the course of discovery and trial preparation or otherwise.

**AND AS FOR A FIRST AFFIRMATIVE DEFENSE**

ChemWerth is not liable to Plaintiff because ChemWerth's performance under the Agreement was excused due to impossibility of performance.

**AND AS FOR A SECOND AFFIRMATIVE DEFENSE**

ChemWerth is not liable to Plaintiff because Plaintiff did not mitigate damages.

**AND AS FOR A THIRD AFFIRMATIVE DEFENSE**

ChemWerth is not liable to Plaintiff because Plaintiff's material breach and/or repudiation of the Agreement discharged ChemWerth's obligations.

**AND AS FOR A FOURTH AFFIRMATIVE DEFENSE**

ChemWerth is not liable to Plaintiff because of ambiguity.

**AND AS FOR A FIFTH AFFIRMATIVE DEFENSE**

There has been no injury in any amount, manner, or form by reason or cause of ChemWerth's alleged acts or omissions.

**AND AS FOR A SIXTH AFFIRMATIVE DEFENSE**

ChemWerth is not liable to Plaintiff because there was failed and/or want of consideration for the Agreement.

**AND AS FOR A SEVENTH AFFIRMATIVE DEFENSE**

In the event Plaintiff seeks punitive/exemplary damages, Plaintiff's punitive/exemplary damages claim is not cognizable under Texas law and, if so, is subject to all statutory and common law caps. Plaintiff's claim for punitive/exemplary damages violates ChemWerth's right to protection from being subjected to excessive fines, as provided in Article I, Section 13 of the Texas Constitution as well as the single-digit ratio between punitive and compensatory damages

set forth in *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003), and *Tony Gullo Motors v. Chapa*, 212 S.W.3d 299 (Tex. 2006).

**AND AS FOR AN EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff is barred from bootstrapping a claim for attorneys' fees under the Declaratory Judgment Act onto its claim for attorneys' fees pursuant to ChemWerth's alleged breach of the Agreement. *See MBM Fin. Corp. v. Woodlands Operating Co., L.P.*, 292 S.W.3d 660, 670 (Tex. 2009).

**AND AS FOR A NINTH AFFIRMATIVE DEFENSE**

ChemWerth is released from payment to Plaintiff because of Plaintiff's own acts and omissions.

**AND AS FOR A TENTH AFFIRMATIVE DEFENSE**

ChemWerth is not liable to Plaintiff because there was a lack of, or only partial, consideration for any compensation due to Plaintiff under the Agreement.

**COUNTERCLAIMS**

1. ChemWerth counterclaims against Plaintiff under the laws of the State of Texas for breach of contract as well as for a declaration of failed performance under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*

2. ChemWerth is a corporation organized under the laws of the State of Connecticut and having a principal place of business at 1764 Litchfield Turnpike, Ste. 202, Woodbridge, Connecticut 06525.

3. Upon information and belief, Plaintiff is a Texas Corporation organized under the laws of the State of Texas.



4. Upon information and belief, Plaintiff has a principal place of business at 2325 Camino Vida Roble, Suite A, Carlsbad, California 92011.

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332, as a result of diversity citizenship between the parties and sufficient amount in controversy.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)(1) and (b)(2). Venue is also proper pursuant to Section VII, Item 1, of the Service Agreement which states: “Exclusive venue for all disputes arising out of relating to this agreement shall be the state and federal courts in Austin, Texas, and each party irrevocably consents to such personal jurisdiction and venue and waives all objections thereto.”

### **Factual Background**

7. On February 1, 2006, ChemWerth entered into a Development Agreement with a Customer regarding development of generic injectable drug products for submission to FDA as Abbreviated New Drug Applications (“ANDAs”). ChemWerth was responsible for providing the Customer with an approved ANDA for the products and performing all analytical and formulation development, manufacture of stability batches, stability testing, and ANDA preparation and filing. ChemWerth was to be compensated through various milestone payments and through a royalty in the event that an approved product was commercially sold.

8. On February 1, 2006 and March 19, 2007, the Development Agreement was amended to include additional injectable ANDA products, one of them being Product S.

9. In and around 2006, Plaintiff held itself out to ChemWerth as having expertise in “the development, manufacture, filing and FDA approval and supply of pharmaceutical products” sufficient to develop generic injection products.

10. ChemWerth sub-contracted Plaintiff to perform all analytical and formulation development, manufacture of stability batches, stability testing, and ANDA preparation and filing for the injectable ANDA products in the Development Agreement, including for Product S.

11. In reliance on Plaintiff's representations regarding its expertise, on or about April 5, 2007, ChemWerth and Plaintiff entered into a Services Agreement, reciting an effective date of March 26, 2007, in which Plaintiff agreed to develop the injectable ANDA products and ChemWerth would compensate Plaintiff by paying to Plaintiff "twenty-five percent (25%) of the amount paid to Chemwerth by any Customer in connection with Product sales for Product in which ChemWerth supplies the drug substance to the Customer (as identified in Exhibit A) and fifty percent (50%) of the amount paid to Chemwerth by any Customer in connection with Product sales for product in which Chemwerth does not supply the drug substance to the Customer (as identified in Exhibit A)."

12. In Section III, Item 2, the Services Agreement states that:

Custopharm provides product development services for pharmaceutical Customers. The product development services may include, but are not necessarily limited to, (a) sourcing of drug substances where Chemwerth or the Customer is not providing or is not providing in a time frame acceptable to the Customer the particular drug substance needed for the development of a drug product; (b) product development services, such as working with contract development laboratories and contract manufacturing organizations (CMO) to assist in the determination of product pricing for product feasibility analysis, oversight of the analytical and formulation development, oversight of the manufacture of the stability/ clinical batches, and oversight of stability testing; (c) preparation and submission of ANDA/ NDA/BLA/ DMF applications in the CTD/ eCTD format to the FDA; (d) Product manufacturing services such as contracting with CMOs per Customer specifications; and (e) addressing of FDA comments pertaining to the submitted ANDA/ NDA/ BLA/ DMF applications.

13. Section III, Item 4, Compensation, of the Services Agreement states that "[w]ithin 30 days after March 31, June 30, September 30, and December 31, beginning after the first Product approval, Chemwerth must deliver to Custopharm a true and accurate written report,

even if no payments are due Custopharm, giving the particulars of the business conducted by Chemwerth and its Customer(s), if any, during the preceding 3 calendar months under this Agreement as are pertinent to calculating Custopharm compensation hereunder.”

14. Section VII, Item 1, Applicable Law, of the Services Agreement states that the agreement “is made under and will be governed by and construed in accordance with the laws of the State of Texas.”

15. Section VII, Item 6, Attorney's Fees, of the Services Agreement states: “In the event that any suit or action is instituted to enforce any provision in this Agreement, the prevailing party shall be entitled to all costs and expenses of maintaining such suit or action, including reasonable attorneys' fees.”

16. Plaintiff knew about ChemWerth's Development Agreement with Customer when it agreed to develop the injectable ANDA products.

17. The products in Exhibit A of the Services Agreement were the products ChemWerth was to develop pursuant to the Development Agreement and included Product S.

18. Plaintiff was aware that ChemWerth would not receive payment from Customer for product sales unless an ANDA was filed and approved.

19. Therefore, Plaintiff knew or reasonably should have known that, for any given product, Plaintiff would have to perform services (b) – (e) of Section III, Item 2 of the Services Agreement in order to receive compensation pursuant to Section III, Item 4.

20. With respect to Product S, ChemWerth understood, based on Plaintiff's representations and the Services Agreement, that Plaintiff agreed to (a) source the drug substance; (b) provide product development services including working with contract development laboratories and contract manufacturing organizations (CMO) to assist in the

determination of product pricing for product feasibility analysis, oversight of the analytical and formulation development, oversight of the manufacture of the stability/ clinical batches, and oversight of stability testing; (c) prepare and submit an ANDA to FDA; (d) contract with a CMO for commercial product manufacture; and (e) address FDA comments pertaining to the submitted ANDA in order to receive compensation from sales of Product S.

21. Plaintiff failed to demonstrate expertise in development, manufacture, filing and subsequent FDA approval and supply of pharmaceutical products and failed to deliver an approvable ANDA product for the products in Exhibit A of the Services Agreement.

22. As a result of Plaintiff's failure to perform, ChemWerth and Customer had to repeat, perform themselves, and/or find another party to perform the services that ChemWerth had contracted to Plaintiff in the Services Agreement and that ChemWerth understood Plaintiff would perform with respect to Product S.

23. Plaintiff failed to perform at the level of expertise that Plaintiff claimed it had with respect to services for Product S.

24. For instance, Plaintiff failed to (a) source the drug substance; (b) provide product development services including working with contract development laboratories and contract manufacturing organizations (CMO) to assist in the determination of product pricing for product feasibility analysis, oversight of the analytical and formulation development, oversight of the manufacture of the stability/ clinical batches, and oversight of stability testing; (c) prepare and submit an ANDA to FDA; (d) contract with a CMO for commercial product manufacture; and (e) address FDA comments pertaining to the submitted ANDA, in order to receive compensation from sales of Product S.

25. ChemWerth and Customer agreed that Plaintiff's performance on Product S was not sufficient.

26. ChemWerth and Customer agreed to take product development responsibilities away from Plaintiff and to find other parties to complete the work.

27. On or about March 11, 2009, ChemWerth and Customer agreed that it was in the parties' mutual best interest for a third party contract manufacturer designated by Customer to manufacture certain products covered by the Development Agreement, including Product S.

28. By around April 2010, Plaintiff had completely stopped working on development of Product S.

29. Customer represented to ChemWerth that it had to spend an additional \$5.5 million in development costs to produce an approvable ANDA product for Product S due to the failures of Plaintiff.

30. During the first quarter of 2014, Customer began to commercially sell product S.

31. Customer reduced ChemWerth's royalty payments for Product S by \$6.0 million to recover the development costs of having a third party perform the work that Plaintiff was supposed to do. As a result, ChemWerth did not receive any royalty monies until fourth quarter 2015.

32. ChemWerth sent a statement of Plaintiff's profit share for Product S beginning in May 2015, after ChemWerth sorted out issues regarding its royalty payments for Product S with Customer.

33. ChemWerth informed Plaintiff it breached Section III(1) of the Services Agreement by failing to perform "in a professional and timely manner and substantially in accordance with the standards and practices of care, skill, and diligence customarily observed by

similar companies under similar circumstances at the time they are rendered.” The consequence was that Customer had to take over the product development, transfer the contract manufacturing and start the project over.

34. Thereafter, ChemWerth sent a statement of Plaintiff’s profit share within 30 days of receiving royalty reports for Product S from Customer.

35. ChemWerth has withheld payment amounts to Plaintiff under the parties’ Services Agreement to recover a portion of its lost royalties. To date, ChemWerth has not even recovered half of lost royalty amounts by withholding payments to Plaintiff.

36. As a result of Plaintiff’s failure to perform its obligations under the Services Agreement, ChemWerth has suffered harm by way of missed milestone payments and decreased royalty payments and lost profits.

#### **Count I – Breach of Contract**

37. ChemWerth incorporates the foregoing paragraphs as if set forth fully herein.

38. There is an enforceable agreement between ChemWerth and Plaintiff by which Plaintiff would exhibit expertise in injectable pharmaceutical product development and was to perform all analytical and formulation development, manufacture of stability batches, stability testing, and ANDA preparation and filing of Product S in order to receive compensation from sales of Product S.

39. Plaintiff failed to tender performance according to the terms of the agreement.

40. Plaintiff failed to exhibit expertise in development, manufacture, filing and subsequent FDA approval and supply of Product S.

41. Plaintiff failed to source the drug substance for Product S in a commercially reasonable manner.

42. Plaintiff failed to provide product development services for Product S in a commercially reasonable manner, including working with contract development laboratories and contract manufacturing organizations (CMO) to assist in the determination of product pricing for product feasibility analysis, oversight of the analytical and formulation development, oversight of the manufacture of the stability/ clinical batches, and oversight of stability testing.

43. Plaintiff failed to develop an approvable ANDA formulation for Product S.

44. Plaintiff failed to prepare and submit an ANDA filing for Product S.

45. Plaintiff failed to contract with a CMO for commercial product manufacture of Product S.

46. Plaintiff failed to address FDA comments pertaining to the submitted ANDA for Product S.

47. Plaintiff's failure to adequately perform its obligations under the agreement is a material breach thereof.

48. As a result of Plaintiff's failure to perform or otherwise satisfy its obligations under the agreement, ChemWerth and Customer have been required to engage others to perform the duties and complete the tasks that Plaintiff should have performed and completed.

49. Plaintiff's failure to adequately perform caused substantial delay and increased costs to achieve the launch of Product S, and such delay and increased costs have resulted in withheld and/or reduced royalty payments to ChemWerth.

50. ChemWerth has been damaged by Plaintiff's breach of contract.

51. Plaintiff's failure to perform was a proximate cause of ChemWerth's damage.

52. By reason of the foregoing, ChemWerth has been damaged by at least \$6.0 million, and in such further amounts as may be proven at trial.

53. ChemWerth is entitled to restitution of its damages as a result of Plaintiff's material breach.

**Count II – Promissory Estoppel**

54. ChemWerth incorporates the foregoing paragraphs as if set forth fully herein.

55. Plaintiff made a clear and definite promise to ChemWerth that Plaintiff had expertise in injectable product development and would deliver an ANDA approvable product to ChemWerth for Product S.

56. Plaintiff made a clear and definite promise to ChemWerth that, for Product S, Plaintiff would (a) source the drug substance; (b) provide product development services including working with contract development laboratories and contract manufacturing organizations (CMO) to assist in the determination of product pricing for product feasibility analysis, oversight of the analytical and formulation development, oversight of the manufacture of the stability/ clinical batches, and oversight of stability testing; (c) prepare and submit an ANDA to FDA; (d) contract with a CMO for commercial product manufacture; and (e) address FDA comments pertaining to the submitted ANDA.

57. Plaintiff knew or reasonably should have expected that ChemWerth would act in reliance on Plaintiff's promises.

58. Plaintiff made those representations to induce ChemWerth to rely upon them and sign the Services Agreement.

59. ChemWerth, not knowing that Plaintiff's representations were false, reasonably relied upon them to its detriment, signing the Services Agreement.

60. Plaintiff breached its promises, failing to exhibit expertise and commercial reasonable performance in the development of Product S by failing to (a) source the drug



substance; (b) provide product development services including working with contract development laboratories and contract manufacturing organizations (CMO) to assist in the determination of product pricing for product feasibility analysis, oversight of the analytical and formulation development, oversight of the manufacture of the stability/ clinical batches, and oversight of stability testing; (c) prepare and submit an ANDA to FDA; (d) contract with a CMO for commercial product manufacture; and (e) address FDA comments pertaining to the submitted ANDA.

61. As a direct and proximate result of Plaintiff's actions, ChemWerth has been injured in the amount of at least \$6.0 million.

62. Enforcement of Plaintiff's promise is the only way to avoid injustice to ChemWerth.

63. Plaintiff therefore is liable to ChemWerth in promissory estoppel in the amount of \$6.0 million plus interest.

### **Count III - Attorney's Fees**

64. ChemWerth incorporates the foregoing paragraphs as if set forth fully herein.

65. ChemWerth is entitled to recover reasonable and necessary attorneys' fees under the provisions of the Services Agreement as set out in Section VII, Item 6, which provides: "In the event that any suit or action is instituted to enforce any provision in this Agreement, the prevailing party shall be entitled to all costs and expenses of maintaining such suit or action, including reasonable attorneys' fees."

66. Under Section VII, Item 6, of the Services Agreement, ChemWerth is entitled to attorneys' fees as the prevailing party in this suit.

67. In the alternative, in the event the Court deems Plaintiff has asserted a proper claim for declaratory relief, ChemWerth seeks its costs and reasonable and necessary attorneys' fees as are equitable and just pursuant to TEX. CIV. PRAC. & REM. CODE § 37.009.

**Count IV – Declaration of Failed Performance**

68. ChemWerth incorporates the foregoing paragraphs as if set forth fully herein.

69. Plaintiff made a clear and definite promise to ChemWerth that, for Product S, Plaintiff would (a) source the drug substance; (b) provide product development services including working with contract development laboratories and contract manufacturing organizations (CMO) to assist in the determination of product pricing for product feasibility analysis, oversight of the analytical and formulation development, oversight of the manufacture of the stability/ clinical batches, and oversight of stability testing; (c) prepare and submit an ANDA to FDA; (d) contract with a CMO for commercial product manufacture; and (e) address FDA comments pertaining to the submitted ANDA.

70. Plaintiff agreed that, for Product S, Plaintiff would (a) source the drug substance; (b) provide product development services including working with contract development laboratories and contract manufacturing organizations (CMO) to assist in the determination of product pricing for product feasibility analysis, oversight of the analytical and formulation development, oversight of the manufacture of the stability/ clinical batches, and oversight of stability testing; (c) prepare and submit an ANDA to FDA; (d) contract with a CMO for commercial product manufacture; and (e) address FDA comments pertaining to the submitted ANDA for Product S and, in consideration, would be compensated by receiving fifty percent (50%) of the amount paid to Chemwerth by Customer in connection with sales of Product S.

71. Plaintiff failed to exhibit expertise and commercially reasonable efforts in development, manufacture, filing and subsequent FDA approval and supply of Product S.

72. Plaintiff failed to source the drug substance for Product S in a commercially reasonable manner.

73. Plaintiff failed to provide product development services including working with contract development laboratories and contract manufacturing organizations (CMO) to assist in the determination of product pricing for product feasibility analysis, oversight of the analytical and formulation development, oversight of the manufacture of the stability/ clinical batches, and oversight of stability testing for Product S in a commercially reasonable manner.

74. Plaintiff failed to develop an approvable ANDA formulation for Product S.

75. Plaintiff failed to prepare and submit an ANDA filing for Product S.

76. Plaintiff failed to contract with a CMO for commercial product manufacture of Product S.

77. Plaintiff failed to address FDA comments pertaining to the submitted ANDA for Product S.

78. ChemWerth seeks a declaration that Custopharm has failed to perform services for Product S and that, as a result, Plaintiff is prevented from enforcing compensation under the Services Agreement and/or enforcing any other agreement between the parties regarding Product S.

79. In the alternative, ChemWerth seeks a declaration that ChemWerth may reduce any compensation owed to Custopharm for Product S to recover for work on Product S that had to be repeated a result of Custopharm's failed performance.

**Prayer for Relief**

WHEREFORE, PREMISES CONSIDERED, ChemWerth respectfully asks the Court award ChemWerth the following relief:

- (a) for a judgment that Plaintiff take nothing by its claims against ChemWerth;
- (b) for a dismissal of Plaintiff's claims against ChemWerth with prejudice;
- (c) Compensatory damages in the amount of \$6.0 million;
- (d) for ChemWerth's costs in this action according to law;
- (e) for pre- and post-judgment interest according to law;
- (f) for ChemWerth's reasonable and necessary attorneys' fees; and
- (g) for such other and further relief as ChemWerth may be entitled to in law or equity.

**JURY DEMAND**

ChemWerth demands a trial by jury on all claims and issues so triable.

Respectfully Submitted,

/s/ Gene S. Winter

Gene S. Winter (admitted *pro hac vice*)

[gwinter@ssjr.com](mailto:gwinter@ssjr.com)

Alyson J. DiLena (admitted *pro hac vice*)

[adilena@ssjr.com](mailto:adilena@ssjr.com)

Bojuan Deng (admitted *pro hac vice*)

[jdeng@ssjr.com](mailto:jdeng@ssjr.com)

ST. ONGE STEWARD JOHNSTON & REENS,  
LLC

986 Bedford Street

Stamford, Connecticut 06905-5619

Telephone: 203-324-6155

Facsimile: 203-327-1096

Email: [litigation@ssjr.com](mailto:litigation@ssjr.com)

John M. Jackson  
Texas State Bar No. 24002340  
[jjackson@jw.com](mailto:jjackson@jw.com)  
Christopher Mugica  
Texas State Bar No. 24027554  
[cmugica@jw.com](mailto:cmugica@jw.com)  
Noah M. Galton  
Texas State Bar No. 24078531  
[ngalton@jw.com](mailto:ngalton@jw.com)  
JACKSON WALKER L.L.P.  
100 Congress Avenue, Suite 1100  
Austin, Texas 78701  
(512) 236-2000 Telephone  
(512) 236-2002 Facsimile

**ATTORNEYS FOR DEFENDANT  
CHEMWERTH, INC.**

**CERTIFICATION OF SERVICE**

I hereby certify that on January 15, 2016, a copy of the foregoing **CHEMWERTH'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS** was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system and by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may access this filing through the Court's CM/ECF System.

/s/ Alyson J. DiLena

Alyson J. Dilena